

molecule comprises 34 contiguous bases of nucleotide sequence from SEQ ID NO:1. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least in claim 1 as originally filed and on page 5, line 5.

Claim 2 has been amended to recite that the stringent hybridization conditions are highly stringent hybridization conditions. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 4, lines 6-12.

Claim 4 has been added to specifically recite expression vectors comprising the nucleic acid sequence of SEQ ID NO:1. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least at page 13, lines 5-6.

Claim 5 has been added to specifically recite host cells comprising the expression vectors of claim 3. Support for this claim can be found throughout the specification as originally filed, with particular support being found at least from page 10, line 32 to page 11, line 5.

It will be understood that no new matter is included within the amended or newly added claims.

III. Oath/Declaration

The Action notes that the declaration is defective because it does not identify the mailing address of inventor Glenn Friedrich. Applicants submit herewith a supplemental declaration in compliance with 37 C.F.R. § 1.67(a), which identifies the application by application number and filing date.

IV. Objection

The Action next objects to the abstract of the application as being non-descriptive. Applicants point out that numerous issued U.S. Patents have an abstract **identical** to the present abstract. Specifically, Applicants direct the Examiner's attention to issued U.S. Patent Nos. 6,433,153, 6,441,153, 6,441,154, 6,444,456 and 6,448,388. As issued U.S. Patents are presumed to meet all necessary PTO requirements, Applicants submit that the present abstract must also meet all necessary PTO requirements.

Applicants request that, since the objection has been overcome, this objection be withdrawn.

V. **Claim 3**

Applicants note for the record that while the Office Action Summary indicates that claims 1-3 are each rejected, none of the rejections in the present Action include or concern claim 3. As claim 3 is an independent claim, claim 3 should have been allowed in the present Action. Applicants respectfully request an indication of the proper status of claim 3 in the next communication from the Patent and Trademark Office in this case.

VI. **Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph**

The Action first rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

35 U.S.C. § 112, first paragraph, requires that the specification contain a written description of the invention. The Federal Circuit in *Vas-Cath Inc. v. Mahurkar* (19 USPQ2d 1111 (Fed. Cir. 1991); "*Vas-Cath*") held that an "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*." *Vas-Cath*, at 1117, emphasis in original. However, it is important to note that the above finding uses the terms reasonable clarity to those skilled in the art. Further, the Federal Circuit in *In re Gosteli* (10 USPQ2d 1614 (Fed. Cir. 1989); "*Gosteli*") held:

Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.

Gosteli at 1618, emphasis added. Additionally, *Utter v. Hiraga* (6 USPQ2d 1709 (Fed. Cir. 1988); "*Utter*"), held "(a) specification may, within the meaning of 35 U.S.C. § 112 ¶1, contain a written description of a broadly claimed invention without describing all species that claim encompasses" (*Utter*, at 1714). Therefore, all Applicants must do to comply with 35 U.S.C. § 112, first paragraph, is to convey the invention with reasonable clarity to the skilled artisan.

Further, the Federal Circuit has held that an adequate description of a chemical genus "requires a precise definition, such as by structure, formula, chemical name or physical properties" sufficient to distinguish the genus from other materials. *Fiers v. Sugano*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993;

"*Fiers*"). *Fiers* goes on to hold that the "application satisfies the written description requirement since it sets forth the . . . nucleotide sequence" (*Fiers* at 1607). In other words, provision of a structure and formula - the nucleotide sequence - renders the application in compliance with 35 U.S.C. § 112, first paragraph.

More recently, the standard for complying with the written description requirement in claims involving chemical materials has been explicitly set forth by the Federal Circuit:

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. *Univ. of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Thus, a claim describing a genus of nucleic acids by structure, formula, chemical name or physical properties sufficient to allow one of ordinary skill in the art to distinguish the genus from other materials meets the written description requirement of 35 U.S.C. § 112, first paragraph. As further elaborated by the Federal Circuit in *Univ. of California v. Eli Lilly and Co.*:

In claims to genetic material ... a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art cannot, as one can do with a fully described genus, visualize or recognize the identity of members of the genus. (Emphasis added)

Thus, as opposed to the situation set forth in *Univ. of California v. Eli Lilly and Co.* and *Fiers*, the nucleic acid sequences of the present invention are not distinguished on the basis of function, or a method of isolation, but in fact are distinguished by structural features - a chemical formula, *i.e.*, the *sequence itself*.

Using the nucleic acid and amino acid sequences of the present invention (as set forth in the Sequence Listing), the skilled artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided. Polynucleotides comprising at least 34 contiguous nucleotides from the nucleotide sequence of SEQ ID NO:1 are within the genus of the instant claim, while those that lack this structural feature lie outside the genus. Claim 1 thus meets

the written description requirement.

For each of the foregoing reasons, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, has been overcome, and request that the rejection be withdrawn.

VII. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that is not described in the specification in such a way as to enable one skilled in the art to make and/or use the claimed invention. Applicants respectfully traverse.

The Action states that “the specification does not enable the skilled artisan to use the claimed polynucleotide because the specification fails to provide a written description of a polynucleotide that has at least 24 contiguous bases of the corresponding polynucleotide sequence” (Action at page 3; emphasis added). Applicants first point out that it is well established that the written description and enablement requirements of 35 U.S.C. § 112, first paragraph, are separate requirements. Therefore, Applicants submit that the present rejection of claim 1 as allegedly not enabled because of an alleged lack of written description support is completely improper. Second, even if properly applied, Applicants submit that as claim 1 does in fact meet the written description requirement, as discussed in Section VI, above, the present rejection of claim 1 as allegedly not enabled because of an alleged lack of written description support has been overcome. Third, and more to the point, Applicants submit that the present invention is clearly enabled, and thus the present rejection of claim 1 as allegedly not enabled is improper, based in part upon the failure to follow the case law regarding practical enablement, on the failure to attribute adequate weight to the details in the specification, and on the technical knowledge already present in the art.

A. Enablement is Established by Enabling Any Practical Use

The § 112 rejection, as applied against the nucleic acid compositions, is completely misplaced. It has long been established that composition claims are enabled by defining any practical use of the claimed compound. *In re Nelson*, 126 USPQ 242 (CCPA 1960); *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1995). “The enablement requirement is met if the description enables any mode of making

and using the invention." *Johns Hopkins Univ. v. CellPro, Inc.*, 47 USPQ2d 1705, 1719 (Fed. Cir. 1998), citing *Engel Indus., Inc. v. Lockformer Co.*, 20 USPQ2d 1300, 1304 (Fed. Cir. 1991).

As detailed in the specification, the claimed DNA segments have numerous practical uses, including, but not limited to, their use in recombinant expression, in various hybridization techniques, in antibody generation, and in numerous cloning embodiments. Where the DNA segments are used in recombinant expression, there is absolutely no requirement that the expressed protein or polypeptide be enzymatically active. In fact, the specification sets forth various uses for proteins and peptides without enzymatic activity, *e.g.*, in antibody generation. The requirements are only that a skilled artisan be able to make and use the DNA segments without undue experimentation (§ 112, first paragraph) and that the product have some practical utility (§ 101). The Action does not question the ability of an artisan to practice recombinant expression techniques, so the § 112 requirement is met. As the instant nucleic acids may be used in various embodiments that do not require enzymatic activity, the § 101/§ 112 requirements are also met.

All that is required to comply with § 112, first paragraph, is for the specification to teach how to make and use the claimed invention so that it may be practiced without undue experimentation. *In re Borkowski and Van Venrooy*, 164 USPQ 642 (CCPA 1970). In *In re Brana*, (34 USPQ2d 1436 (Fed. Cir. 1995), "*Brana*"), the Federal Circuit admonished the P.T.O. for confusing "the requirements under the law for obtaining a patent with the requirements for obtaining government approval to market a particular drug for human consumption". *Brana* at 1442. The Federal Circuit went on to state:

At issue in this case is an important question of the legal constraints on patent office examination practice and policy. The question is, with regard to pharmaceutical inventions, what must the applicant provide regarding the practical utility or usefulness of the invention for which patent protection is sought. This is not a new issue; it is one which we would have thought had been settled by case law years ago.

Brana at 1439, emphasis added. The choice of the phrase "utility or usefulness" in the foregoing quotation is highly pertinent. The Federal Circuit is evidently using "utility" to refer to rejections under 35 U.S.C. § 101, and is using "usefulness" to refer to rejections under 35 U.S.C. § 112, first paragraph. This is made evident in the continuing text in *Brana*, which explains the correlation between 35 U.S.C. §§ 101 and 112, first paragraph. The Federal Circuit concluded:

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

Brana at 1442-1443, citations omitted. In assessing the question of whether undue experimentation would be required in order to practice the claimed invention, the key term is "undue", not "experimentation". *In re Angstadt and Griffin*, 190 USPQ 214 (CCPA 1976). The need for some experimentation does not render the claimed invention unpatentable. Indeed, a considerable amount of experimentation may be permissible if such experimentation is routinely practiced in the art. *In re Angstadt and Griffin, supra*; *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988; "Wands").

In terms of compositions, the Office has not provided evidence showing that one of ordinary skill in the art would reasonably doubt the direction in the specification concerning the various uses of the claimed nucleic acid molecules of the present invention. Therefore, a sufficient *prima facie* case of deficient teaching has not been established, and the burden has not been properly shifted to the Applicants to provide rebuttal evidence.

However, although the burden has been improperly shifted to Applicants, the following section is provided describing the detailed guidance and teaching provided in the specification for the claimed compositions and the technical knowledge present in the art regarding the use of nucleic acids.

B. The Specification Provides Adequate Guidance and Teaching

There is sufficient knowledge and technical skill in the art for a skilled artisan to be able to make and use the claimed DNA species in a number of different aspects of the invention entirely without further details in a patent specification. Additionally, the present specification includes significant details of techniques to accomplish many aspects of the present invention, including recombinant expression,

site-specific mutagenesis, *in situ* hybridization, and properly incorporates standard texts into the specification, such as Sambrook *et al.* (*Molecular Cloning, A Laboratory Manual*) and Ausubel *et al.* (*Current Protocols in Molecular Biology*) to provide even further guidance to the skilled artisan. Incorporation of material into the specification by reference is proper. *Ex parte Schwarze*, 151 USPQ 426 (PTO Bd. App. 1966). The § 112, first paragraph rejection is thus *prima facie* improper:

As a matter of patent office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Marzocchi & Horton, 169 USPQ 367, 369 (CCPA 1971), emphasis as in original. In any event, an alleged lack of express teaching is insufficient to support a first paragraph rejection where one of skill in the art would know how to perform techniques required to perform at least one aspect of the invention. As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands, supra*. In fact, it is preferable that what is well known in the art be omitted from the disclosure. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986). As standard molecular biological techniques are routine in the art, such protocols do not need to be described in detail in the specification.

Furthermore, a specification "need describe the invention only in such detail as to enable a person skilled in the most relevant art to make and use it." *In re Naquin*, 158 USPQ 317, 319 (CCPA 1968); emphasis added. The present claims are thus enabled as they are supported by a specification that provides sufficient description to enable the skilled person to make and use the invention as claimed.

C. Claim 1 is Enabled

As detailed in the sections above, all aspects of the enablement rejection under 35 U.S.C. § 112, first paragraph have been overcome. Applicants therefore respectfully request that the rejection be withdrawn.

VIII. Rejection of Claims 1 and 2 Under 35 U.S.C. § 112, Second Paragraph

The Action next rejects claims 1 and 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Action rejects claim 1 as allegedly indefinite based on the term "NHP". While Applicants submit that the term does not render the claim indefinite, the term "NHP" has been removed from the claim. Applicants therefore request withdrawal of this rejection.

The Action rejects claim 2 as allegedly indefinite based on the term "stringent hybridization conditions", because the specific hybridization and washing conditions are not recited in the claim. Applicants stress that "a claim need not 'describe' the invention, such description being the role of the disclosure". *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). However, while Applicants submit that the term is sufficiently definite, as a number of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art, solely in order to progress the case more rapidly toward allowance the claim has been revised to specifically recite "highly" stringent hybridization conditions. As the specification provides specific teaching regarding "highly stringent hybridization conditions", at least at page 4, lines 6-12, Applicants submit that revised claim 2 even more clearly meets the requirements of 35 U.S.C. § 112, second paragraph. Applicants therefore request withdrawal of this rejection.

IX. Rejection of Claim 1 Under 35 U.S.C. § 102(a)

The Action next rejects claim 1 under 35 U.S.C. § 102(a), as allegedly anticipated by Kaplan *et al.* (June, 1999, Am. J. Physiol. 276: L1027-L1036; "Kaplan"). While Applicants do not necessarily agree with the present rejection, as claim 1 has been amended to recite an isolated nucleic acid molecule comprising at least 34 contiguous bases of nucleotide sequence from SEQ ID NO:1, which is neither taught nor suggested by Kaplan, Applicants submit that the rejection of claim 1 under 35 U.S.C. § 102(a) has been overcome, and respectfully request withdrawal of the rejection.

X. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such

favorable action is respectfully requested. Should Examiner Mitra have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

February 28, 2003

Date

David W. Hibler

David W. Hibler
Agent for Applicants

Reg. No. 41,071

LEXICON GENETICS INCORPORATED
8800 Technology Forest Place
The Woodlands, TX 77381
(281) 863-3399



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PATENT TRADEMARK OFFICE

Exhibit A

Clean Version of The Pending Claims in U.S. Patent Application Ser. No. 09/667,380

1. (Amended) An isolated nucleic acid molecule comprising at least 34 contiguous bases of nucleotide sequence from SEQ ID NO:1.
2. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:
 - (a) encodes the amino acid sequence shown in SEQ ID NO: 2; and
 - (b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.
3. An expression vector comprising a polynucleotide sequence encoding the amino acid sequence shown in SEQ ID NO: 2.
4. (New) The expression vector of claim 3, wherein the polynucleotide comprises the nucleotide sequence of SEQ ID NO:1.
5. (New) A host cell comprising the expression vector of claim 3.

Exhibit B

Marked Up Version of Amended Claims in U.S. Patent Application Ser. No. 09/667,380

1. (Amended) An isolated nucleic acid molecule comprising at least [24] 34 contiguous bases of nucleotide sequence [first disclosed in the NHP gene described in] from SEQ ID NO: 1.
2. (Amended) An isolated nucleic acid molecule comprising a nucleotide sequence that:
 - (a) encodes the amino acid sequence shown in SEQ ID NO: 2; and
 - (b) hybridizes under highly stringent conditions to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof.
3. An expression vector comprising a polynucleotide sequence encoding the amino acid sequence shown in SEQ ID NO: 2.
4. (New) The expression vector of claim 3, wherein the polynucleotide comprises the nucleotide sequence of SEQ ID NO:1.
5. (New) A host cell comprising the expression vector of claim 3.